

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>6476-WO</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/DK 03/ 00419</b>	International filing date (day/month/year) <b>20/06/2003</b>	(Earliest) Priority Date (day/month/year) <b>21/06/2002</b>
Applicant <b>NOVO NORDISK A/S</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 7 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

## 1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.



the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:



contained in the international application in written form.



filed together with the international application in computer readable form.



furnished subsequently to this Authority in written form.



furnished subsequently to this Authority in computer readable form.



the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.



the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ Certain claims were found unsearchable (See Box I).

3. ☐ Unity of Invention is lacking (see Box II).

## 4. With regard to the title,



the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

## 5. With regard to the abstract,



the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

## 6. The figure of the drawings to be published with the abstract is Figure No.



as suggested by the applicant.



because the applicant failed to suggest a figure.



because this figure better characterizes the invention.



None of the figures.

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/DK 03/00419

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61K38/36 A61P7/04

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, MEDLINE, BIOSIS, EMBASE, CHEM ABS Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 48635 A (BESMAN MARC ;BJORNSON ERIK (US); PIKAL MICHAEL (US); CARPENTER JOH) 24 August 2000 (2000-08-24) page 9 -page 12 page 29 -page 30; table 12 ---	1-54
X	WO 93 00807 A (CRYOLIFE INC) 21 January 1993 (1993-01-21)  page 1, line 4 - line 7 page 3, line 11 - line 23 page 6, line 25 - line 28 page 7, line 10 - line 20 page 8, line 27 page 8, line 31	1,7-29, 31,32, 35,36, 38-43, 45-54
Y	---	1-54
	--- -/-	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"S" document member of the same patent family

Date of the actual completion of the international search

1 October 2003

Date of mailing of the international search report

20.10.03

Name and mailing address of the ISA

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## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/DK 03/00419

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	<p>WO 94 26286 A (KABI PHARMACIA AB ;OESTERBERG THOMAS (SE); FATOUROS ANGELICA (SE)) 24 November 1994 (1994-11-24) page 6, line 8 - line 32 page 7, line 4 - line 19 abstract -----</p>	1-54

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/DK 03/00419

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0048635	A	24-08-2000	
		AU 2884300 A	04-09-2000
		BR 0008405 A	30-04-2002
		CA 2362927 A1	24-08-2000
		CN 1399560 T	26-02-2003
		CZ 20012996 A3	13-03-2002
		EP 1154796 A1	21-11-2001
		JP 2003520764 T	08-07-2003
		WO 0048635 A1	24-08-2000
		US 6586573 B1	01-07-2003
WO 9300807	A	21-01-1993	
		AU 2309692 A	11-02-1993
		WO 9300807 A1	21-01-1993
WO 9426286	A	24-11-1994	
		AT 218354 T	15-06-2002
		AU 681883 B2	11-09-1997
		AU 6659794 A	12-12-1994
		CA 2161350 A1	24-11-1994
		CN 1122573 A ,B	15-05-1996
		CZ 9502869 A3	15-05-1996
		DE 69430745 D1	11-07-2002
		DE 69430745 T2	17-10-2002
		DK 700299 T3	23-09-2002
		EE 3118 B1	15-10-1998
		EP 0700299 A1	13-03-1996
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		FI 955305 A	06-11-1995
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		JP 8509745 T	15-10-1996
		NO 954457 A	07-11-1995
		NZ 266031 A	24-04-1997
		PL 311567 A1	19-02-1996
		PT 700299 T	29-11-2002
		RU 2142290 C1	10-12-1999
		WO 9426286 A1	24-11-1994
		SK 138395 A3	05-02-1997
		US 5962650 A	05-10-1999
		ZA 9402251 A	01-11-1994

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Claims Nos.: 47-50

Claims 47-50 relate to methods for treatment of the human or animal body by surgery or by therapy/diagnostic methods practised on the human or animal body/Rule 39.1.(iv). Nevertheless, a search has been executed for these claims. The search has been based on the alleged effects of the compounds/compositions.

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/DK 03/00419**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 47-50  
because they relate to subject matter not required to be searched by this Authority, namely:  
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims..
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 03/00419

## Box III TEXT OF THE ABSTRACT (Continuation of Item 5 of the first sheet)

The invention relates to chemically as well as physically stable compositions comprising Factor VII or a Factor VII-related polypeptide such that these compositions can be stored, handled and used at room temperature. The compositions comprises at least one stability agent selected from:

- a) a combination of an antioxidant and mannitol;
- b) a combination of methionine and a polyol;
- c) a combination of a saccharide and mannitol;
- d) a combination of sucrose and a polyol ; and
- e) methionine.

The antioxidant is e.g. homocysteine, cysteine, cystathionine, methionine or glutathione. The saccharide is e.g. sucrose, dextrose, lactose, maltose, trehalose, cyclodextrins, maltodextrins or dextrans. The polyol is e.g. mannitol, sorbitol or xylitol.